REMARKS/ARGUMENTS

Claims 1-29 and 31-48 are pending. Claim 1 has been amended to clarify the intent. This amendment finds support in the specification in paragraphs [0008] and [0021]. Claims 4 and 5 have been amended to replace "two helices" with "double-helix" and "three helices" with "triple-helix," respectively. Support for this amendment is found in the specification in paragraph [0024]. Claim 46 has been amended to correct a typographical error. Support for this amendment is found in claim 46, as filed. No new matter was introduced by these amendments. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

Preliminarily, Figures 3C and 3D have been alleged to be unacceptable because allegedly new matter has been added. Office Action, page 2. The Examiner contends that "[a] double helix is generally regarded as having two opposing coils that are wound in opposite directions." *Id.* Applicants respectfully disagree. A common usage of the term "double-helix" is illustrated in Exhibit A. In Exhibit A, a "DNA double helix," one example of a double helix, is described as "two antiparallel strands that are complementary in their nucleotide sequence are paired in a right-handed double helix." Exhibit A, Bruce Alberts *et al.*, *Molecular Biology of the Cell* 101 (3rd ed. 1994). It is clear from this usage that the "antiparallel strands" are a separate feature from the "right-handed double helix." Further, requiring that the helices of the specification with multiple strands have "opposing coils that are wound in opposite directions" would not be consistent with the disclosure of "triple- and multiple-helices configurations" where it would be impossible to have all the strands running in opposing directions. Applicants therefore assert that the well-known definition of "double helix" does not require "opposing coils." Applicants request that Figures 3C and 3D be accepted and the requirement for new drawings withdrawn.

The drawings have been further objected to under 37 C.F.R. § 1.83(a) because allegedly they do not show every feature of the invention specified in the claims. Office Action, page 2. Specifically, the Examiner alleges that the "two helices" and "three helices" of claims 4 and 5 are not shown in the drawings. Applicants disagree, however solely to expedite prosecution, claims 4 and 5 have been amended to recite "double-helix" and "triple-helix," respectively. The wording of these claims is now that used in the description of Figure 3 and relates to that figure. Specification, paragraph [0026].

Claim 46 has been objected to due to informalities in claim language. Office Action, page 3. Claim 46 has been amended to correct a typographical error.

Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. §102 Rejections

I. Claims 1-3, 7-12, 17-19,40, 41, and 43-45 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ragheb *et al.* (U.S. Pat. No. 6,096,070; "Ragheb"). Office Action, page 4. The Examiner alleges that Ragheb discloses multiple features of these claims. Applicants respectfully traverse.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

Ragheb does not disclose each and every element of claims 1-3, 7-12, 17-19,40, 41, and 43-45. Claim 1, as amended, recites "the stent supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing." The Examiner asserts that "[w]hen a certain amount of force is applied to the aneurysm site, by a vise or during a car accident for example, the stent of Ragheb will contract." Office Action, page 14. Claim 1 now recites that the stent will contract "when the aneurysmal site contracts due to healing," a force much less that that applied by a vise or during a car accident. Ragheb does not disclose a stent which will contract given that small amount of force. Ragheb also does not disclose a stent which engages "the inwardly-facing surface of the vessel wall."

Ragheb does not disclose a stent which has a helical configuration," as recited in claim 2. Figure 7, which is referred to at the cite referred to by the Examiner, is not a true helix because of the longitudinal member. Ragheb, Col. 15 l. 56.

Ragheb does not disclose a stent which comprises "at least one helix," as recited in claim 3, because the stents described in Ragheb are not true helices.

Ragheb does not disclose a stent wherein "the therapeutic agent is covalently linked to the polymer" as recited in claim 10 wherein the stent comprises the polymer. Ragheb does not disclose a therapeutic agent covalently linked directly to the polymer which comprises the stent.

Therefore, since the Examiner has not established a *prima facie* case of anticipation of claims 1-3, 7-12, 17-19,40, 41, and 43-45 by Ragheb, it is respectfully requested that the Examiner withdraw this ground of rejection.

II. Claims 1, 31, 38, and 39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hunter *et al.* (U.S. Pat. No. 5,716,981; "Hunter"). Office Action, page 6. The Examiner alleges that Hunter discloses polymers including polylactic acid, polycaprolactone, microsphere and size ranges up to approximately 120 microns, and release profiles of the therapeutic agent including about 1% to about 25% of the therapeutic agent released in the first 10 days. *Id.*

Hunter does not disclose every element of claim 1. Hunter does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. The Examiner does not indicate where in Hunter these features are disclosed.

Therefore, since the Examiner has not established a *prima facie* case of anticipation of claims 1, 31, 38, and 39 by Hunter, it is respectfully requested that the Examiner withdraw this ground of rejection.

35 U.S.C. § 103 Rejections

I. Claims 4 and 5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb in view of Solem *et al.* (U.S. Pat. No. 6,210,432; "Solem"). Office Action, page 7. The Examiner alleges that Solem discloses a stent with two helices and three helices. *Id.* Applicants respectfully traverse.

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application." See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. *See id.* Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. See *WMS Gaming Inc. v. International Game Technology*, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. *See id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. *See id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000).

If any one of these three factors is not met, the PTO has failed to establish a *prima facie* case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

There is no motivation to combine Solem with Ragheb to make the inventions of claims 3 and 4. Ragheb relates to a coated implantable medical device adapted for introduction into the vascular system, esophagus, trachea, colon, biliary tract or urinary tract. Ragheb, abstract. Solem relates to a device for the treatment of mitral annulus dilatation. The mitral annulus is the fibrous ring of the heart which surrounds the mitral valve. The devices disclosed in Solem are for a different purpose than those disclosed in Ragheb, therefore one of ordinary skill in the art would not be motivated to combine discloses of the two references.

Further, there is no motivation to combine the disclosure relating to the devices of Solem with the disclosure related to the devices of Ragheb and no reasonable expectation of success in the combination because the devices are disclosed to operate by different principles. Ragheb

discloses that an intravascular stent is "placed in the dilated segment of the artery to mechanically prevent abrupt closure and restenosis." Ragheb, col. 2 ll. 27-31. Thus, the stent of Ragheb applies a radial force to the artery walls. In contrast, the mitral annulus devices of Solem are disclosed to be "forced into a stretched or extended state" before attachment to the wall of the coronary sinus, then providing "a bending and/or shortening" of the device. Solem, col. 2 ll. ll. 36-43; col. 4 ll. 25-39. Therefore, the device of Solem operates by providing primarily a lengthwise force. Therefore, one of ordinary skill in the art would not be motivated to combine the characteristics of a device that provides a lengthwise force to create one that provides a radial force, and would have no reasonable expectation of success in the combination.

Ragheb and Solem, either alone or in combination, do not disclose every element of claims 4 and 5. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Solem does not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 4 and 5 over Ragheb in view of Solem, it is respectfully requested that the Examiner withdraw this ground of rejection.

II. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb in view of Eisert (U.S. Pat. Pub. No. 2005/0192664; "Eisert"). Office Action, page 7. The Examiner alleges that Eisert discloses a pH sensitive polymer. Applicants respectfully traverse.

Claim 14 recites a list of pH-sensitive polymers suitable for use in the intravascular treatment devices of the invention. The Examiner admits that these polymers are not disclosed in Eisert, but rather claims that they are well known in the art. Office Action, page 8. Applicants disagree and respectfully request that the Examiner produce authority for this assertion.

Claim 16 recites a list of temperature-sensitive polymers suitable for use in the intravascular treatment devices of the invention. The Examiner admits that these polymers are not disclosed in Eisert, but rather claims that they are well known in the art. Office Action, page 8. Applicants disagree and respectfully request that the Examiner produce authority for this assertion.

Ragheb and Eisert, either alone or in combination, do not disclose every element of claims 13-16. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Eisert does not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 13-16 over Ragheb in view of Eisert, it is respectfully requested that the Examiner withdraw this ground of rejection.

III. Claims 6, 10, and 20-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb. The Examiner alleges the elements of claims 6, 10 and 20-27 are well known in the art. Applicants respectfully traverse.

Ragheb does not disclose every element of claims 6, 10, and 20-27. As discussed above, Rabheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1.

Regarding claim 6, the Examiner states that he considers self-expanding stents to be well known in the art. Office Action, page 9. Applicants disagree and respectfully request that the Examiner produce authority for this assertion.

Regarding claim 10, the Examiner suggests that it would be within the purview of a person having ordinary skill in the art at the time of the invention to modify Ragheb's polymer stent to include covalently linked heparin directly to the base material. Office Action, page 9. However, given the disclosure of Ragheb, one of ordinary skill in the art would not be motivated to make this modification, and would have no expectation of success in the modification. Ragheb discloses that the vascular device comprises at least one layer of bioactive material posited on one surface of the structure. Ragheb, col. 7 ll. 55-58. One of ordinary skill in the art would not be motivated to covalently bond heparin directly to the base material and then add at least one layer over it, as the heparin would not be exposed to the blood, and would have no reasonable expectation of success in the modification.

Regarding claims 20-27, the Examiner admits that the therapeutic agents in these claims are not disclosed by Ragheb. Office Action, page 9. The Examiner asserts that these therapeutic agents are well known in the art for the treatment of various vascular deficiencies. Office

Action, page 9. Applicants disagree and respectfully request that the Examiner produce authority for this assertion.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 6, 10, and 20-27 over Ragheb, it is respectfully requested that the Examiner withdraw this ground of rejection.

IV. Claims 28 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb in view of Sparer *et al.* (U.S. Pat. Pub. No. 2004/0127978; "Sparer"). Office Action, page 10. The Examiner alleges that Sparer discloses the therapeutic agent being contained in a microsphere associated with a polymer. *Id.* Applicants respectfully traverse.

Ragheb and Sparer, either alone or in combination, do not disclose every element of claims 28 and 29. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Sparer does not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 28 and 29 over Ragheb in view of Sparer, it is respectfully requested that the Examiner withdraw this ground of rejection.

V. Claims 31, 32, and 34-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb in view of Vallana *et al.* (U.S. Pat. Pub. No. 2003/0028242; "Vallana"). Office Action, page 10. The Examiner alleges that Vallana discloses polymers that are used as carriers for therapeutic coatings. Office Action, page 11. Applicants respectfully traverse.

Ragheb and Vallana, either alone or in combination, do not disclose every element of claims 31, 32, and 34-38. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Vallana does not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 31, 32, and 34-38 over Ragheb in view of Vallana, it is respectfully requested that the Examiner withdraw this ground of rejection.

VI. Claims 39 and 48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb in view of Vallana further in view of Sparer. Office Action, page 11. Applicants respectfully traverse.

Ragheb, Vallana and Sparer, either alone or in combination, do not disclose every element of claims 39 and 48. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Vallana and Sparer, alone or in combination, do not make up for this deficiency.

Ragheb, Vallana and Sparer, alone or in combination, do not disclose a time release coating which "releases from about 1% to about 25% of the therapeutic agent within 10 days after deployment," as recited in claim 39. The Examiner cites Figure 1 of Sparer for this disclosure, however, the graph in this figure does not have data up to 10 days. Office Action, page 12; Sparer, Figure 1. The x-axis in Figure 1 is in the square root of days, and only has data up to "2," or 4 days. Therefore, there is no disclosure in Sparer that up to 10 days the released therapeutic agent would not go over 25%. Ragheb and Vallena, alone or in combination, do not have disclosure that makes up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 39 and 48 over Ragheb in view of Vallana further in view of Sparer, it is respectfully requested that the Examiner withdraw this ground of rejection.

VII. Claim 33 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ragheb in view of Vallana further in view of Tartaglia *et al.* (U.S. Pat. No. 5,637,113; "Tartaglia"). Office Action, page 12. The Examiner alleges that Tartaglia discloses a therapeutic coating consisting of a film from 0.0015 inch to 0.002 inch thick. *Id.* Applicants respectfully traverse.

Ragheb, Vallana and Tartaglia, either alone or in combination, do not disclose every element of claim 33. As discussed above, Ragheb does not disclose a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Vallana and Tartaglia, alone or in combination, do not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claim 33 over Ragheb in view of Vallana further in view of Tartaglia, it is respectfully requested that the Examiner withdraw this ground of rejection.

VIII. Claims 42, 46, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gerberding (U.S. Pat. No. 6,790,224; "Gerberding") in view of Falotico *et al.* (U.S. Pat. No. 2003/0060877; "Falotico"). Office Action, page 13. The Examiner alleges that Gerberding discloses a method of treating an aneurysm comprising deploying to an aneurysm site, and deploying a stent graft to exclude the aneurysm which a substantial portion of the device of claim 1 being disposed between the stent graft and the wall of the aneurysm. *Id.* The Examiner further alleges that Falotico discloses a therapeutic agent on the inner surface of the stent and a therapeutic agent being inactive until in comes into contact with an activating agent. *Id.* Applicants respectfully traverse.

Gerberding and Falotico, either alone or in combination, do not disclose every element of claims 42, 46, and 47. Gerberding does not disclose the deployment of a stent which "supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing," as recited in claim 1. Falotico does not make up for this deficiency.

Gerberding and Falotico, either alone or in combination, do not disclose "deploying a stent graft to exclude the aneurysm where a substantial portion of device of Claim 1 is disposed between the stent graft and the wall of the aneurysm" as recited in claim 46. The Examiner cites items 16 and 18 of Figure 2 in Gerberding as disclosing these features, however this figure does not disclose a stent, as in claim 1, and an additional stent graft, as in claim 46. Further, in claim 46, it is clear that the deployment of the stent graft is a separate step from the deployment of the device of claim 1, while in Gerberding, items 16 and 18 in Figure 2 are clearly joined and deployed together. Falotico does not make up for this deficiency.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 42, 46, and 47 over Gerberding in view of Falotico, it is respectfully requested that the Examiner withdraw this ground of rejection.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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